

STATE OF WASHINGTON DEPARTMENT OF HEALTH

Olympia, Washington 98504

DEPARTMENT OF HEALTH WASHINGTON STATE BOARD OF PHARMACY

MEETING AGENDA

January 26, 2007

Department of Labor & Industries
Auditorium
7273 Linderson Way SW
Tumwater, WA 98501
Board Office: (360) 236-4825

CONVENE

Chair Asaad Awan convened the meeting at 9:16 a.m. on January 26, 2007.

Board Members present:

Gary Harris, RPh George Roe, RPh Rebecca Hille, Vice-Chair Rosemarie Duffy, RN Susan Teil-Boyer, RPh Vandana Slatter, PharmD

Staff Members present:

Joyce Roper, Assistant Attorney General Lisa Salmi, Acting Executive Director Tim Fuller, Pharmacy Consultant Andy Mecca, Pharmacy Consultant Grace Cheung, Chief Investigator Jim Lewis, Pharmacist Investigator Doreen Beebe, Program Manager

CONSENT AGENDA

- **1.1** Pharmacist License Application Approval
 - Joseph Shultz Nuclear Pharmacist
- **1.2** Pharmacy & Other Firm Application Approval
 - New & Closed Pharmaceutical Firms 10/31/2006 thru 12/22/2006
- **1.4** Pharmacy Tech Training Program Approval
 - Daniel Garcia Everest Institute in San Antonio TX
 - Robin Crozier Trinity College in Fairfield CA
 - Ann Crisanto Centro Escolar University in Manila, Philippines

- Norman Beck San Joaquin Valley College in Bakersfield CA
- 1.5 Collaborative Drug Therapy Agreement Acceptance
 - Nancy Hecox Dyspepsia Management
 - Sonia Allen Anticoagulation Therapy Management
 - Keith Fongemie Pseudo Products
- **1.8** Board Minute Approval December 14, 2006

Items 1.3 – Pharmacy Technician Application Approval; 1.6 Automated Drug Dispensing Device Acceptance; and 1.7 Sample Distribution Requests were deleted from the consent agenda. **MOTION**: Susan Teil-Boyer moved that the Board approve 1.1, 1.2, 1.4, 1.5, and 1.8 of the consent agenda. Rebecca Hille second. **MOTION CARRIED 6-0.**

REPORTS

Lisa Salmi reported:

- December budget overview the report did not include Attorney General Support expenses
 accrued in the last few months due to work related to a disciplinary hearing scheduled for
 February. Ms. Salmi acknowledged that the Board is considerably overspent in AG services.
 The Board will receive additional allotment authority to cover these expenses. Under spent
 in salaries due to vacancies: Executive Director, Board clerical support position, Central
 Washington Investigator and part-time Precursor Investigator.
- May explore funding for permanent over-hire for an additional investigator. **ACTION**: Ms. Salmi will bring the proposal back to the Board at a future meeting.
- The Board was authorized an increase in allotment authority to supplement the budget increase requested by the Washington Recovery Assistance Program for Pharmacy (WRAPP). An increase of approximately \$40,000 over a period of four years. Representatives of the WRAPP program expressed concerns that if program participants are required to pay fees additional staff would be needed to manage/monitor fee collection. In addition, WRAPP believed the added costs may pose a hardship for some program participants.
- NABP Annual Conference currently the budget would support sending all members of the Board to the May conference in Portland. The budget will need to be re-evaluated as we get closer to May.
- The Planning Session in February will provide an opportunity for the Board to develop proposals and justification for additional allotment to fund special projects/interests for consideration by the Department of Health in developing the 07-09 biennial budgets.
- Auditors continuing to met with the disciplinary and credentialing staff. The auditors' final report will be submitted in July.
- eLicensing, the new credentialing/disciplinary system implementation date is scheduled for February 2008.
- Staff working on workgroups for eLicensing, working with auditor, and preparing analysis on the proposed rule for pharmacies'/pharmacists' responsibilities.
- Jim Doll, Tim Fuller and Ms. Salmi participated in the strategic national stockpile tabletop exercise involving reception, storage and staging facility. Full scale exercise planned for October 2007 in Eastern Washington
- Methamphetamine Workgroup met last week Donna Dockter will continue to represent the Board. The Workgroup must report their findings and recommendations to the Legislature in November 2007.
- A request to increase the salary for the Executive Director position will be considered by the Washington Management Services Committee in February.

- Board authorized a summary suspension of a pharmacist for diverting drugs from her place of employment and providing those drugs to another person.
- Ms. Salmi acknowledged Joyce Roper for her continued assistance.

Board Members

Rebecca Hille briefly discussed her participation in the Tuesday "Meet Me" conference calls held by the Department of Health, Health Professions Quality Assurance office regarding legislation with possible impact to multiple professions.

Susan Teil-Boyer reported:

- In Pierce County all the hospitals are getting together to discuss impending avian flu and the coordination of staff, patient care and distribution of Tami flu.
- Attended the American Society of Health-System Pharmacists (ASHP) mid-year clinical
 meeting in early December. Ms. Teil-Boyer participated with representatives from several
 state boards of pharmacy sharing issues and concerns. She was asked to provide an update
 on Washington's rule making activities regarding pharmacy technician certification
 examination.

Assistant Attorney General

Joyce Roper reported:

• Washington Supreme Court issued a ruling, based on the U.S. Constitution, on the Ongom case dealing with the burden of proof required for disciplinary cases. The court held that the standard of proof for all licensed health care professionals shall be clear and convincing evidence rather than a preponderance of the evidence. Clear and convincing evidence is a "highly probable" standard as opposed to the more common civil case standard of preponderance of the evidence, which is a more likely than not standard, but is lower than the criminal standard of beyond a reasonable doubt. The office of the Attorney General will seek a review by the U.S. Supreme Court on behalf of the Department of Health (*Petition for Writ of Certiorari*).

Washington and Oklahoma are the only two states where there has been a ruling that the United States constitution requires a higher burden of proof. There are other jurisdictions where the higher burden of proof has been established by the legislature.

Pharmacist Consultant/Investigator

Andy Mecca reported:

- January 12th Mr. Mecca met with Board Investigator Stan Jeppesen, and University of Washington School of Pharmacy Professor Tom Hazlet to design the March review law course offered to pharmacy students to prepare for the Multistate Pharmacy Jurisprudence Examination (M PJE).
- January 22nd Mr. Mecca attended a meeting regarding the implementation of opioid guidelines campaign. This group has begun talks on developing an educational pilot project and is looking for physicians interested in participating.
- Working on putting together a presentation on frequently asked questions for the Washington State Pharmacy Association meeting on February 10th.
- Mr. Mecca will conduct a review of proposals made in April and July of 2006 approving offsite pharmacy practices, which allowed Washington licensed pharmacists to work at their home. The goal is to ensure that prior decisions are consistent with the Board's decision in December. ACTION: Mr. Mecca will report back to the Board with recommendations after reviewing the December request.

Chief Investigator

Grace Cheung reported:

- Updated the Board on the recruitment process for the Central Washington Investigator position. One of the two applicants has withdrawn.
- Andy Mecca gave a presentation to the Veterinary Board of Governors on appropriate handling of medications.
- Board Investigators Jim Doll and Dick Morrison provided technical assistance on the appropriate handling of medications to the Skagit County Jail.
- Ms. Cheung and Dick Morrison participated in the MPJE State Specific law questions review. Forty-four states participated in the review this year. They reviewed over 1700 questions in the existing pool; deleted 46 out-dated or duplicated questions and approved 116 new questions out of a pool of 1100 resulting in a net gain of 70 questions.
- Investigators' Meeting: Asked Board members to check their calendars to identify who might be available to attend. Dates as follows:
 - o March 8, Susan Teil-Boyer
 - \circ June 6-7
 - September 12 13, George Roe
 - o December 5 -6

Program Manager

Doreen Beebe reported:

Ms. Beebe facilitated a workgroup tasked with developing strategies to avoid scheduling
conflicts for 2008 meeting/disciplinary calendars for Board and Commissions. Four of
the large Boards and Commissions are on 6-week meeting intervals with Thursdays'
business meetings and Fridays' disciplinary hearing. In 2007, the intervals have
consistently fallen on the same weeks resulting in scheduling difficulties for staff
attorneys, AAG advisors, prosecutors and health law judges.

PRESENTATION

PDX-Rx.com.

Chair Awan introduced Senior Vice-President Buck Stevens to present PDX-Rx.com proposal.

Mr. Stevens explained that PDX-Rx.com operates a Washington licensed pharmacy in Fort Worth, Texas and is proposing to provide central fill pharmacy services to community pharmacies in Washington State.

Highlights

- Drug Utilization Review originating pharmacy
- Common database
- Newest version of systems imaging at both locations
- Common prescription number originating pharmacy identified on label
- Originating pharmacy retains prescription/refill, and conducts product verification
- Originating pharmacy benefits:
 - o Retains ownership of original prescription/refill
 - Ability to purchase medication by tablet
 - Specialty pharmacy services
 - o An alternative for high cost/slow moving medications

Medication Therapy Management

Concerns

- Mailing prescriptions directly to the patient from the central-fill pharmacy is not permitted
 where there is not a common ownership between the originating pharmacy and the centralfill pharmacy.
- Patients must be informed of option not to utilize central fill services.
- Representative stock requirements of Washington Administrative Code not fulfilled by central-fill services.
- Final check pharmacist at the central-fill pharmacy must have the ability to view the prescription.
- Dispensing pharmacist is accountable for the dispensing the correct prescription to the correct patient.

MOTION: George Roe moves that the Board approve the PDX-Rx.com Central-fill proposal upon receipt of written confirmation of contract compliance with the following conditions:

- The Central Fill pharmacy is not permitted to mail prescriptions directly to the patient must be sent directly to the originating pharmacy.
- The contract must require that the originating pharmacy post signage informing patients of their option not to participate in the central-fill process.
- The dispensing and central fill pharmacies must share common electronic files or have appropriate technology to allow secure access to sufficient information necessary or required to dispense or process the prescription. It is expected that the central-fill final check pharmacist have the ability to view an image of the prescription.

Susan Teil-Boyer 2nd. **MOTION CARRIED**. 6-0

The Board asks that staff (Andy Mecca) work with PDX-Rx.com to ensure that the conditions of the approval is clearly communicated.

DISCUSSTION

2007 Legislative Updates

- HB1100 Background Checks National electronic fingerprint checks, if deemed necessary.
- HB1101 Amends Uniform Disciplinary Act Sanction Guidelines
- HB1103 Amends Uniform Disciplinary Act Shifts authority to investigate/charge from the Boards/Commissions to the Secretary of Health. MOTION: Susan Teil-Boyer moved that the Board send a letter to the Secretary sharing the Board's concerns regarding this bill and the potential impact to public health and safety. Rebecca Hille second. MOTION CARRIED. 6 0.
- HB1104 Amends Uniform Disciplinary Act Mandatory reporting; authorizes the revocation of a health care provider's license for three separate courses of unprofessional conduct over a ten-year period and restricts the type of cases that can be resolved by Stipulation to Informal Disposition.
- HB1300 Department of Health's request legislation that amends the Uniformed Disciplinary Act. The bill proposes to change to the process for denying applications, shifting the burden of proof to the licensee rather than the department. This legislation would allow the department to issue a notice of determination that an applicant could appeal; allows for the permanent revocation of a license for egregious violations; and creates

- a citation and fine process to ensure documents are produced in response to an investigative request.
- HB1553 Electronic Prescription Monitoring Program Requires the establishment of a real-time web-based monitoring program, requires dispensers to submit prescription information electronically; requires the department to seek federal grants to cover costs; and prohibits the department from collecting fees or taxing practitioners or pharmacists to cover implementation or maintenance costs; provides a list of persons who may access the information and allows us to share information with the Department of Social and Health Services. Issues: funding, security and implementation timeline.

HB1487 & HB1719 - Several bills increasing the penalties/provisions for pseudoephedrine.
 SB5631 - Wholesale Distribution of Prescription Drugs – 1st reading today – program has not yet analyzed this bill.

Planning Session

Lisa Salmi distributed the Board's two year goals and strategic action plan developed at the 2004 planning session. The Board asks that the planning session include:

- A review/evaluation of past goals and set goals for the next year.
- Evaluation of rule making priorities.

Pharmacy Standards in Correctional Facilities

The practice of pharmacy in correctional facilities is unique. Staff recently reviewed the laws and rules used to evaluate the standards of pharmacy services provided in correctional facilities. They found that the Board does not have adequate standards in rule to evaluate pharmaceutical services in correctional facilities. The Board was asked to prioritize the rule making process to move this issue to the top of the rule making agenda.

MOTION: Susan Teil-Boyer stated that the Board acknowledges the importance of this issue and moved that the Board authorized staff to begin stakeholder work to examine to the need to develop rules regulating pharmacy standards in correctional facilities. Rebecca Hille second. **MOTION CARRIED.** 6-0

The Use of Pharmacy Technicians to Collect Medication Histories

The Board was asked to provide direction to staff when answering recent inquires regarding the scope of practice of a pharmacy technician in collecting medication histories from patients in an emergency room setting.

Ms. Teil-Boyer provided additional background on this practice. Effective January 2006, organizations accredited by the Joint Commission are required to implement medication reconciliation processes as part of the National Patient Safety Goal. Upon entering the hospital patient's current medications are obtained and documented for review by the provider and can also be reviewed by a pharmacist. Due to limited resources, some hospitals are using nurses, and pharmacy technicians to collect medication histories.

Practice Settings:

• Emergency Room - Discretionary task. Pharmacy Technicians are <u>not</u> permitted to take medication history. Patient medication history is acted upon by a practitioner.

• Ambulatory & Outpatient – Nondiscretionary task. Pharmacy Technicians may take medication history from a patient, under the supervision of a pharmacist. Patient medication history is not acted upon by a practitioner.

The Board affirms that collecting medication histories from patients in an emergency room setting is outside a pharmacy technician's scope of practice.

<u>Continuing Education – Recognizing Accredited Certificate Programs</u>

MOTION: Susan Teil-Boyer moved that the Board recognizing accredited certificate programs such as Board Certified Pharmacotherapy Specialist (BCPS), Certified Diabetic Educator (CDE), American College of Clinical Pharmacy (ACCP), Board Certified Psychiatric Pharmacist (BCPP), American Society of Health System Pharmacists (ASHP), Board Certified Oncology Pharmacist (BCOP), Certified Geriatric Pharmacist (CGP) and Pharmacist Self Assessment Mechanism by the National Association of Boards of Pharmacy as acceptable continuing education credit in the year they are earned. Rosemarie Duffy second. **MOTION CARRIED.** 6 – 0.

1.5 CEU's (15 hours) for accredited certificate programs and 0.9 CEU's (9 hours) for Pharmacist Self Assessment Mechanism by NABP.

EXECUTIVE SESSION – CLOSED SESSION

The Board adjourned for Executive Session at 12:00 p.m. to discuss personnel issues and pending litigation.

The Board reconvened at 1:20 p.m.

DISCUSSION Cont'd

Pharmaceuticals from Households: A Return Mechanism

Board Investigator Stan Jeppesen updated the Board on the PH:ARM program and provided a brief summary of the pilot for the audience. Mr. Jeppesen asked the Board to send a letter to the Federal Drug Enforcement Agency (DEA) to request a waiver(s) or other mechanism so that the program can be fully implemented by allowing the collection of controlled substances. A draft was distributed for the Board's review.

Update

- 7 Group Health pilot sites
- Collected 44 buckets (5 gallons each) of materials
- Finalizing incineration process pickup/delivery

MOTION: Susan Teil-Boyer moved that the Board issue a letter to the DEA stating its support for the PH:ARM program and requesting the DEA to authorize the program to collect controlled substances. George Roe second. **MOTION CARRIED**. 6 – 0.

ACTION: Lisa Salmi will send the final draft of the letter to the Board for comments prior to sending to the DEA. The letter will not be sent to the DEA until after the drugs that have been collected are incinerated and staff have assessed the process.

PRESENTATIONS Cont'd

Pharmacy Internship Requirements

Andy Mecca summarized the current pharmacy internship process and then introduced Dr. Tom Hazlet to speak about some of the motivations for change. Dr. Hazlet reminded the Board that 3 student "Fix the Law" presentations in the past suggested changes to the internship process. In addition, the American Council on Pharmaceutical Education (ACPE) has revised its accreditation standards and guidelines for PharmD programs requiring experiential training earlier on in the academic process. The University of Washington will be the first school in the U.S. to be evaluated using the new standards.

Dr. Hazlet shared that the process of evaluating the new ACPE accreditation standards and guidelines has presented an opportunity to review the current Preceptor/Internship processes. Issues include: internship learning experience not well matched to the curriculum; inconsistent or nonexistent training plans for the internship program; and preceptor/intern evaluations that don't identify problems early on in the learning experience.

Suggestion: Of the 1500 internship hours required for licensure, 1200 of which is currently earned as part of the curriculum, apply the remaining 300 hours to structured experiential learning opportunities throughout the academic program.

Issues

- 1. Develop model Intern utilization plans (stages)
- 2. Internship programs referring mechanisms (already in place for clinical rotations)
- 3. Evaluations timely progress reports (competencies)
- 4. Change/eliminate preceptor designation
- 5. Out-of-State Interns
- 6. ACPE does not permit academic credit and pay for the same activities.
- 7. Resources

Dr Hazlet acknowledged Andy Mecca, Bill Fassett, Annie Lam, Stan Webber, and Don Williams for their participation.

The Board has determined that this is a worthwhile project and encourages staff participation.

University of Washington, School of Pharmacy.

Dr. Tom Hazlet introduced the 2nd year pharmacy students who presented to the Board pharmacy law projects on *Acetaminophen Overdose Leading to Hepatic Failure* and suggested solutions.

Presenters: Nicholas Au, Thi Doan, Louisa Dubois, Christi Irons, Rebecca Kingsley, Laura Lutz, Alexander McDonald, and Megan Melchiors.

OPEN FORUM.

No comments.

PRESENTATION OF AGREED ORDER – Orders presented to the Board for consideration.

<u>CLOSED SESSION</u> Case presentations.

<u>Business Meeting Adjourned</u>
There being no further business, the Board adjourned at 2:30 p.m. They will meet again on March 1, 2007 in Kent, Washington.

Doreen E.	Beebe, Program Manager
Appro	oved on March 1, 2007